EN

User manual for the Broncoflex

For single use only

Use by qualified medical staff

Axess Vision Technology

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FRANCE

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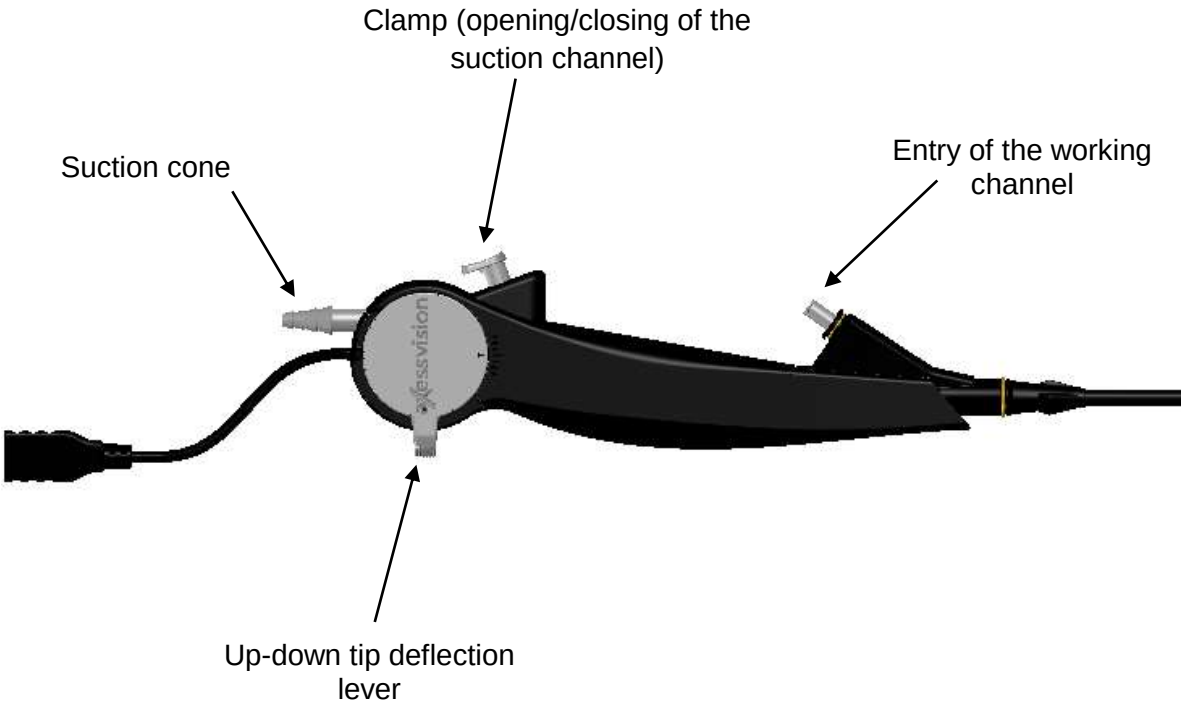

Overview of the Broncoflex®

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You must read this document carefully.

1. Introduction

Scope

This video-bronchoscope has been designed to provide optical visualisation of an adult's airways using a monitor or tablet. The airways include the organs, tissues and organ systems: the nasal passages, windpipe and the bronchial tree beyond the primary bronchi. Instruments are introduced through the mouth or nose when indications consistent with the requirements of the procedure are observed in adult patients.
The Broncoflex must not be used for any other purpose than the one described here.

User manual

This user manual contains key information for the optimum use of this product in complete safety. Read this manual carefully, as well as the manuals of all the other instruments being used, and use them accordingly. Keep all of the user manuals in a safe place that is easy to access. If you have any questions or comments to make about this user manual, please contact Axess Vision Technology.
This manual describes the recommended inspection and preparation procedures prior to using the equipment, as well as those concerning its cleaning and maintenance after use. It does not describe how to carry out a given procedure, nor does it set out to teach a beginner the correct technique or medical aspects concerning the equipment's use. It is up to each medical establishment to make sure that only staff who are fully trained in the theoretical and practical aspects, competent and instructed in how to use endoscopic equipment, antimicrobial agents/processes and the hospital protocol for controlling infections are involved in the sterilisation or otherwise of these medical devices. The known risks and/or potential injuries associated with flexible endoscopic procedures are primarily as follows: perforation, infection and haemorrhage.

It is vital that all of the instructions given in this user manual are followed with the utmost care. Poor understanding of these instructions could cause:

- serious injury or even death in the patient
- serious injuries in the user
- serious injuries in a third party
- damage to the equipment.

Training and qualification of the user

Before the system is supplied, training is given by staff who have been certified by Axess Vision Technology.
If there are official standards concerning the user's qualification for carrying out endoscopy and endoscopic treatments, which have been defined by the medical administration or other official institutions such as the society of endoscopy, they must be complied with.
If there are no such standards, this instrument must only be used by a physician who has been accredited by the head of the hospital's accident prevention department or head of the corresponding department (internal medicine, etc.).
The physician must be capable of carrying out the planned endoscopy and endoscopic treatments in complete safety, in line with the directives set by the society of endoscopy, etc., with account taken of the risks of complications associated with endoscopy and endoscopic treatment. This user manual does not provide any explanations or information about endoscopic techniques in themselves.

Accessories

The accessories used via the working channel, such as biopsy forceps, can have an effect on the performances of the endoscope. If a specific or highly specialised accessory is available from another supplier, please contact Axess Vision Technology to have a compatibility test carried out prior to using it in the endoscope.
The maximum external diameter of an endoscopic accessory must be at least 0.2 mm less than the specified diameter of the working channel of the Axess Vision Technology endoscopes. The functional length of an endoscopic accessory must be about 30 cm more than the functional length of the endoscope.

Substances used

The Broncoflex working channel is compatible with the substances usually used during a bronchoscopic examination.

2. Precautions of use

- Check that the packaging is fully intact prior to use. If the packaging is damaged, the devices it contains must not be used.
- Prior to use, check each Broncoflex consumable for any signs of deterioration. If the product is damaged, do not use the device.
- The product must be handled and used by qualified staff with the utmost care.
- Check that the Up/Down tip deflection lever and handpiece clamp work properly.
- Check that the working channel cap is in place.

- Clean the lens with an optical cloth if necessary.
- When handling the product, make sure the aseptic techniques are followed stringently.
- Should it prove difficult to introduce the Broncoflex into the bronchi or a probe, do not force it, but try to find out why this is the case before continuing.
- Carefully select the size of the intubation probe according to each patient.
- Make sure that the compatibility of the Broncoflex with all of the accessories without electricity supply has been checked prior to use each time.
- Do not use the device while the patient is being administered highly flammable anaesthetic gas.
- Do not use the device during defibrillation.
- The use of the following is strictly prohibited:
- endotherapy accessories with electricity supply, with the bronchoscope,
- active endoscopic accessories (such as laser probes or electrosurgical equipment).
- Handle sharp or pointed tools carefully so as not to damage the flexible tube of the endoscope.
- Make sure there is a similar system to hand as back-up so that the procedure can continue in the event of malfunction.
- The Broncoflex is thrown away in the designated container for contaminated disposable instruments after use.

3. Packaging

The consumable is sterile and delivered ready-to-use in sealed packaging.
The consumables are delivered in a cardboard pack of 5. Inside this pack, each EO sterilised consumable is placed in a single sterile bag.
Make sure you read the label on the top of each individual packaging.

4. Storage precautions

The devices must be kept in their unopened original packaging, in a dry, clean place away from sunlight.
The storage conditions for maintaining an optimum service life of the products are the normal temperature and pressure conditions, i.e. 20°C and 1.013 bar.

5. Device description

The Broncoflex is a disposable bronchoscopic system that is part of an overall system. This system comprises a video-bronchoscope, an electronic processor (called a Box) and a display screen (tablet or monitor).

The Broncoflex's multifunctional handpiece comprises the following:

- a lever for Up/Down tip deflection,
- a control button to activate suction when it is connected to the vacuum network,
- a working channel entry with Luer tip for using tools with a 1.8 mm diameter.

The materials making up this handpiece are as follows: Pebax, Pebd, ULTEM, ABS, PEEK and Polyimide.
The distal end is fitted with a visualisation and lighting system enabling progress through the patient's respiratory system.

Technical characteristics

Type	Broncoflex
Field of view direction	**0°**
Field Angle	**120°**
Field Depth	**3 - 80 mm**
X tip deflection angle (up/down)	**160° / 130°**
Tip deflection radius	**9 mm**
External diameter of the insertion tube	**5.5 mm**
External diameter of the distal tip	**5.5 mm**
Internal diameter of the working channel	**2.1 mm**
Functional length	**600 mm**
Lighting system	**2 leds**
Diameter of the suction tube tip	**5 to 9 mm**
Minimum size of the endotracheal probe (internal diameter)	**7 mm**

Tip deflection lever

There is a tip deflection lever on the handpiece to point Up or Down. The maximum tip deflection angle Up is around 160°, and Down 130°.

Clamping mechanism

Suction with the suction channel is activated by using the control lever.

Working channel

The system comprises a working channel controlled from the control handpiece to the distal tip, which is compatible with existing accessories.
The working channel enables practitioners to insert the standard tools used in defined endoscopic applications, for it has been designed to accommodate the usual sampling forceps. The working channel is connected to the suction channel via a Y-piece union.
A cap for the working channel can be used to seal it, thereby isolating the suction channel and ensuring its efficacy during use. This is supplied with the consumable.

6. Instructions for use

- The device is for single use only. Do not reuse the Broncoflex consumable for there could be a risk of cross-infection.
- Do not use alcohol on the lenses.
- Prior to using the bronchoscope each time, check the parts intended to be introduced into a patient, to ensure there is no unintentional rough surface, sharp or protruding edge that could cause injury.
- Prior to use, check that the endoscopy devices are compatible with all accessories without electricity supply.

Axess Vision Technology shall not be held liable if a patient is injured or the device is damaged through incorrect use of its products.

Procedure

- Connect the endoscope to the Box then turn it on.
- Remove the white protective tube (disposable) before beginning the examination.
- Follow the instructions in the Box's user manual.
- Check that the LEDs and camera work properly by directing them at an object (the palm of your hand for example).
- If the image is blurred, clean the distal end with an appropriate optical cloth (no alcohol).
- Test that the tip deflection works in the Up and Down position according to the angles specified.
- Test the channel sealing by connecting a syringe filled with sterile liquid (e.g. saline solution) to the Luer tip. Check that there are no leaks.
- Connect a tube from the endoscope tip to the suction system (not supplied). Then check that the piston controlling the suction works properly.
- Check that the tools intended for use during the examination are compatible with the Broncoflex and are in satisfactory condition.
- The system is then ready to use.
- Carry out the examination.
- After use, the Broncoflex must be thrown away in the designated container for contaminated disposable devices.

If the Broncoflex needs to be used several times on the same patient, it must be placed in sterile storage conditions. The practitioner is responsible for determining whether or not contamination has occurred in the interval between two uses.
The temperature of the endoscope distal tip can rise to 45°C when the LEDs heat up. Prolonged contact with the mucous membrane can damage it. Putting the device tip in contact with the mucous membrane for long periods is not advised.

7. Safety

Instructions in the event of damaged packaging:

When the cardboard pack is opened, if the packaging ensuring the consumable's sterile barrier is pierced or open, the consumable must not be used as it could have become contaminated by different strains of bacteria.
It must be returned to Axess Vision Technology.

Information concerning the technical factors/characteristics which might pose a risk if the device has to be reused:

The consumable must be thrown away after use to avoid any cross-contamination (hospital-acquired infections, prion diseases, etc.).

Disposing of the consumable:

The consumable must be thrown away in designated bins and containers for contaminated objects. The used equipment must be put into special containers fitted with a lid, and then incinerated.

Contact with the patient

Only the endoscope is considered to be the applied part, and only this part of the equipment must come into contact with the patient.

8. Warranty

The Broncoflex is delivered with a **one-year** warranty from the manufacturing date, which is also the product's validity date.
To avoid any risk of contamination, contaminated medical devices must not be returned under any circumstances. Should a defect be observed on the product, please inform your usual contact person in as much detail as possible so that a customer service form can be completed. If the defect is visible, it is advisable to take photographs of it.
In the event of a proven defect, Axess Vision Technology will replace the product(s).

9. Malfunctions

The LEDs do not light up or there is no image:

The connector is probably not connected properly in the Box.
Check that the connector clicks in properly in the Box and that the Box lights up. Refer to the user manual for how to use the Box.

Obstructed channel:

Clean the working channel using a cleaning brush or rinse it by injecting sterile saline solution into it using a syringe. If you cannot remove the obstruction from the working channel, prepare a new endoscope.

Poor suction:

The valve that is meant to block the biopsy Y-piece union is damaged or assembled incorrectly. Change or refit the valve.

10. What the icons on the Broncoflex label mean

Pictograms	Meaning		Pictograms	Meaning
	For single-use only, do not re-use			Do not resterilise
	Sterilised by ethylene oxide (EO)			Product manufacturer
	Do not use if the packaging is open			Number of items in the packaging
	Consult the user manual for how to use this product			Serial number
	Product expiry date			Batch number
	Keep away from sunlight and UV rays			Conformity marking as per the European Medical Device Directive (90/42/EEC) together with the identification number of the notified body: SGS
	Keep dry			Fragile
	Storage temperature			

11. Standards applied

The Broncoflex works in accordance with the following regulations:

- European Medical Device Directive (93/42/EEC)
- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC 60601-2-18 Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2: Medical electrical equipment – Part 1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

12. Manufacturer's and distributor's contact details

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Axess Vision Technology attests to the conformity of its equipment in terms of both its design and manufacture according to the applicable standards.

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